Level of Triggers Concept (RP17)

Institutional Level - IRB example

Levels

System Default

Institution: These rules apply to all Clinical Trials

Trigger Title

Trigger Category: IRB AE Reporting Triggers

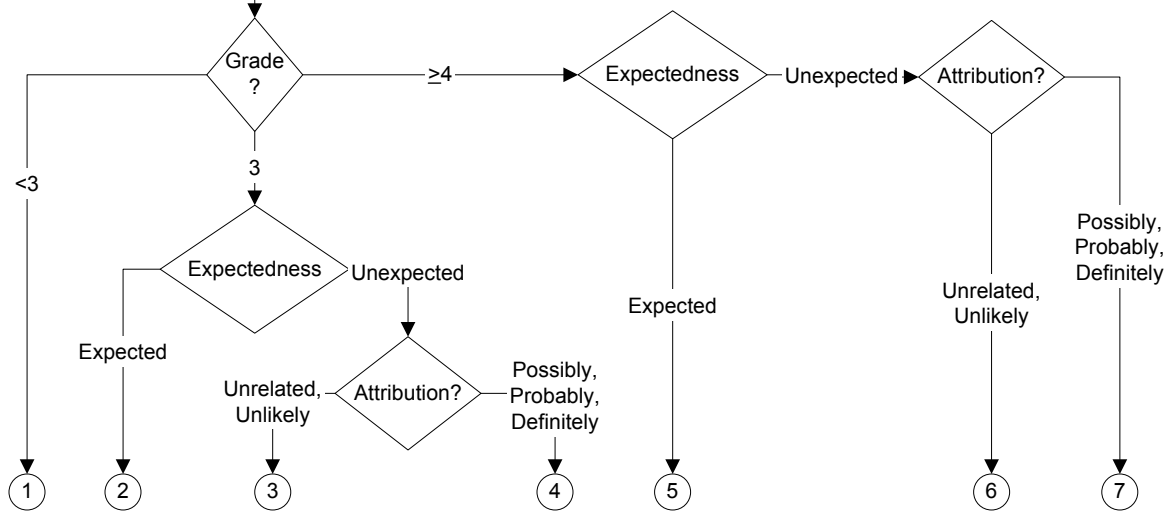
Trigger Category: IRB AE Reporting Triggers
Trigger Title: IRB Trigger 1; Description: Expected, grade < 3
Trigger Title: IRB Trigger 2; Description: Expected, grade =3
Trigger Title: IRB Trigger 3; Description; Unexpected, attribution unlikely, grade =3
Trigger Title: IRB Trigger 4; Description; Unexpected, attribution unlikely, grade =3
Trigger Title: IRB Trigger 5; Description; Expected, grade ≥4
Trigger Title: IRB Trigger 6; Description; Unexpected, attribution unlikely, grade ≥4
Trigger Title: IRB Trigger 7; Description; Unexpected, attribution possibly, grade ≥4

Title DSMB AE Reporting Triggers → FP18 A

Trigger Rules (What to Report)

Invoke: AE State = Created

*Issue - Need to confirm when to invoke and stop the trigger



Trigger Attributes:
AE Category
AE Term
Sponsor
Phase
Grade
Hospitalization
Expectedness
Attribution

Timing & Escalation Rules (When & Who)

Action: Notify CRA, Nurse Coordinator to follow-up
Timing: Day 0 (immediately)
Who: CRA, Nurse Coordator
How: Email & application notification on log-in

1, 2, 3 → **Action:** Summerize in Protocol Continuation Report
Timing: notify 30 days prior to protocol IRB annual review date
Who: Protocol Staff
How: Email & application notification on log-in

5, 6 → **Action:** Wait for DSMB report then submit IRB AE report
Timing: Business Reporting Days = 10
Who: Protocol Staff
How: Email, application notification on log-in

4, 7 → **Action:** Submit IRB AE report (Use Case 4.1)
Timing: Business Reporting Days = 5
Who: Protocol Staff
How: Email, application notification on log-in

RP19 B

Level of Triggers Concept (RP18)

Institutional Level - DSMB example

Levels

RP17 A

Institution: These rules apply to all Clinical Trials

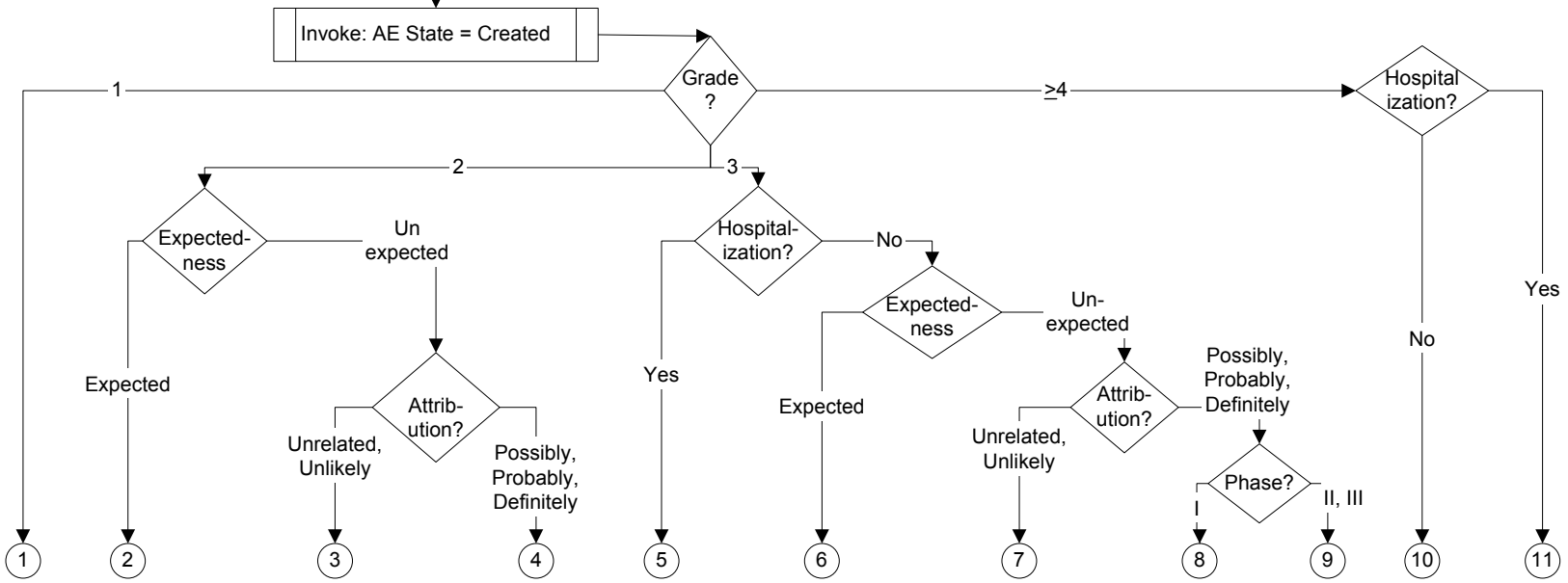
Trigger Title

Trigger Category: DSMB AE Reporting Triggers

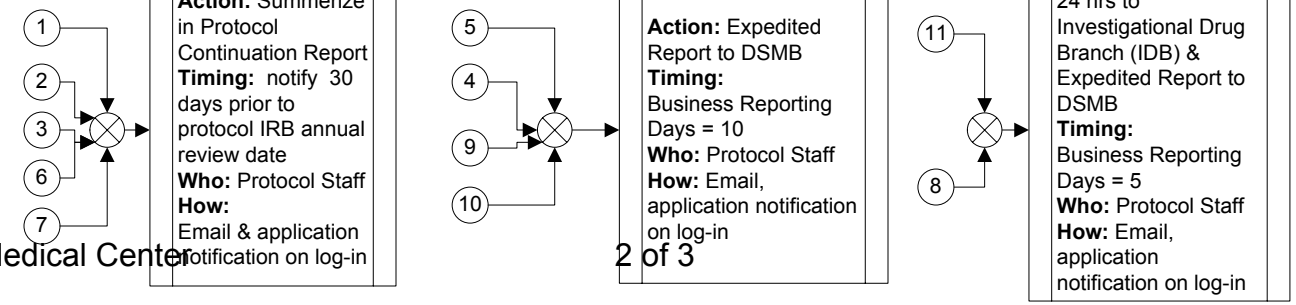
Trigger Title: DSMB Trigger 1; Description: grade = 1
Trigger Title: DSMB Trigger 2; Description: Expected, grade = 2
Trigger Title: DSMB Trigger 3; Description: Unexpected, attribution unlikely, grade = 2
Trigger Title: DSMB Trigger 4; Description: Unexpected, attribution possibly, grade = 2
Trigger Title: DSMB Trigger 5; Description: Hospitalized, grade = 3
Trigger Title: DSMB Trigger 6; Description: Not hospitalized, Expected, grade =3
Trigger Title: DSMB Trigger 7; Description: Not hospitalized, Unexpected, attribution unlikely, grade = 3
Trigger Title: DSMB Trigger 8; Description: Not hospitalized, Unexpected, attribution possibly, Phase I, grade = 3
Trigger Title: DSMB Trigger 9; Description: Not hospitalized, Unexpected, attribution possibly, Phase II/III, grade = 3
Trigger Title: DSMB Trigger 10; Description: Not hospitalized, grade > 4
Trigger Title: DSMB Trigger 11; Description: Hospitalized, grade >4

Trigger Rules (What to Report)

Trigger Attributes:
AE Category
AE Term
Sponsor
Phase
Grade
Hospitalization
Expectedness
Attribution



Timing & Escalation Rules (When & Who)



Example for a 10 day report period

RF17 B

RP19

Notification Timing & Escalation Rules				
Day	**Escalation Rule**	**Role to Notify**	**Mechanism**	**Message**
1	N/A	CRA	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
3	Data not completed	CRA	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
5	Data not completed	PI	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
9	Data not completed	PI	Email & Application	Subject: IRB Reportable AE Text: AE created on [date] IRB AE reporting required. AE data needs to be completed for report generation. [Notice #] & [Report due in [x] days
15	Data completed Report submitted Follow-up	PI	Email & Application	Subject: IRB Reportable AE Follow-Up Text: AE created on [date] IRB AE reporting required. AE data needs to be completed on [date].